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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,219	03/28/2001	Jean-Michel Bernardon	016800-425	7072

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EXAMINER	
ROBINSON, BINTA M	

ART UNIT	PAPER NUMBER
1625	18

DATE MAILED: 08/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/719,219	Applicant(s) BERNARDON ET AL.	
	Examiner Binta M. Robinson	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 15-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13 and 15-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *17* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Detailed Action

The office action at paper no. 18 is vacated because it erroneously responded to the amendment at paper no. 13/C rather the amendments at paper nos. 15 and 16. The 112, second paragraph rejection of claim 10 at paper no. 14 is withdrawn in light of applicant's remarks at paper no. 15.

(new rejection)

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim(s) 1 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. The phrase "amino acid residue » in line 12, claim 1, page 4 of the amendment 13/C is indefinite. It is not clear what derivatives or residues of the amino acids are being claimed.

B. The phrase, "amino acid residues are selected from the group consisting of residues derived from lysine, glycine, and aspartic acid" in claim 10, line 1-2, page 6 of amendment 10/B. is indefinite. The phrase is indefinite because it is unclear as to what moieties are actually being claimed, since only a residue of the claimed amino acids are being claimed, and it is unclear as to what residues are being claimed. The specification on page 6 only explains the phrase "amino acid residue" as being for example, a moiety from one to 20 amino acids of L or D configuration which constitutes mammalian proteins. If the applicant can point out where in the specification, amino

acid residues are delineated by actual specific chemical moieties, then this language would be a better substitute than "amino acid residues". However, it does not appear that the applicant has clearly defined in the specification what amino acid residues are in terms of specific chemical moieties.

(Old Rejection)

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13 and 15-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, does not provide enablement for R2 and R3 taken together with the adjacent aromatic ring, to form all 5 or 6 membered saturated rings optionally substituted with methyl groups and/or optionally interrupted with an oxygen or sulfur atom, R' and R" taken together to form, with the nitrogen atom, all heterocycle rings, and does not enable electron withdrawing groups such as nitro existing in the ortho position on the aralkyl rings as claimed in claims 6 and 7. In claims 6 and 7, it is impossible for electron withdrawing groups to exist in the ortho position on an aralkyl or aryl ring. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claims as recited are broader than the scope of enablement. The specification lacks direction or guidance for placing all of the

alleged products in the possession of the public without inviting more than routine experimentation. The applicant is referred to ***In re Wands***, 858 f.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in ***Ex parte*** Foreman 230 USPQ 546 (Bd. Of App. And Inter 1986).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1)the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art 6) the amount of direction provided by the inventor 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F. 2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

In terms of the breadth of the claims, for R2 and R3 taken together with the adjacent aromatic ring, R' and R" taken together, and aryl or aralkyl optionally substituted as claimed encompass a much wider Markush grouping of radicals than those radicals tested. In terms of the second Wands factor, the nature of the invention is that these compounds are useful as cosmetic compositions for body and hair hygiene. In terms of the fifth Wands factor, the level of predictability in the art is low because the applicant does not conduct any tests of these compounds for their effects as cosmetic compositions. In terms of the sixth Wands factor, the amount of direction provided by the inventor is poor, because the applicant does not synthesize compounds

where R2 and R3 or R' and R" come together to form any other heterocycle ring other than nicotinate. The applicant also does not synthesize compounds for example, where two nitro groups exist in the ortho position. The applicant also does not test the effects of these compounds as cosmetics. In terms of the seventh Wands factor, the applicant provides no working examples of these compounds for their effects as cosmetics. In terms of the 8th Wands factors, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of predictability in the art of the invention, and the poor amount of direction provided by the inventor. Taking the above factors into consideration, it is not seen where the instant claim is enabled by the instant application. There is no reasonable assurance that the different heterocyclic ring systems combined would have the alleged utilities. See In re Fouche, 169 USPQ 429 (CCPQ 1971)

(modified rejections)

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 15 is rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement for the method of treating all diseases claimed or reasons of record at paper no. 14. Many of these diseases are unrelated and require modes of actions that cannot be addressed by a pharmaceutical

drug. An agonist of a receptor site and an antagonist of a receptor site without a preliminary screening test gives no clear indication that the compounds would have the alleged properties. Cancer or precancerous states, alopecia, cicatrisation disorders, stretch marks cannot be prevented with pharmaceutical drugs. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The claims as recited are broader than the scope of enablement.

The applicant is referred to ***In re Wands***, 858 f.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in ***Ex parte*** Foreman 230 USPQ 546 (Bd. Of App. And Inter 1986).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1)the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art 6) the amount of direction provided by the inventor 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F. 2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).
In terms of the second Wands factor, the nature of the invention is that these compounds are useful as cosmetic compositions for body and hair hygiene. In terms of the fifth Wands factor, the level of predictability in the art is low because the applicant

does not conduct any tests of these compounds for their effects as cosmetic compositions. In terms of the sixth Wands factor, the amount of direction provided by the inventor is poor, because the applicant does not synthesize compounds where R2 and R3 or R' and R" come together to form any other heterocycle ring other than nicotinate. The applicant also does not synthesize compounds for example, where two nitro groups exist in the ortho position. The applicant also does not test the effects of these compounds as cosmetics. In terms of the seventh Wands factor, the applicant provides no working examples of these compounds for their effects as cosmetics. In terms of the 8th Wands factors, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of predictability in the art of the invention, and the poor amount of direction provided by the inventor. Taking the above factors into consideration, it is not seen where the instant claim is enabled by the instant application.

Response to Applicant's Remarks

112, first paragraph rejection of claim 15

The applicant traverses the rejection of claim 15 under 112, first paragraph enablement alleging that the examiner has not provided any analysis of the Wands factors in the office action. However, the examiner has provided analysis of the Wands factors, and has demonstrated how specific Wands factors are not met. For example, the fifth, sixth, and seventh Wands factors are not met because the applicant does not conduct any tests of these compounds for their effects as cosmetic compositions. Therefore the level of predictability in the art cannot be determined and

the amount of direction provided by the inventor is poor. Without providing specific examples of the effects of actual compounds on the diseases and conditions claimed, it is not possible to know how the effects of these compounds vary with slight changes in the compound structure that fit within the genus claimed.

The applicant also alleges that the examiner has not provided any support for the position that many of these diseases cannot be treated with a pharmaceutical drug.

However, the examiner is not claiming that many of these diseases cannot be treated with a pharmaceutical drug, but that many of the vast array of diseases being claimed in claim 15 cannot be treated with one drug. The applicant has not demonstrated that these vast array of diseases can be treated with any of the compounds being claimed. The applicant is claiming diseases that have many unrelated mechanisms and hence different receptor sites that will be the target of treatment. Some of the categories of diseases being claimed are so broad as to encompass a vast array of conditions and diseases such as a "keritinization disorder, which has a bearing on differentiation and on proliferation". For example, it is not clear what diseases are defined by the category "dermatological complaints associated with a keratinization disorder with an inflammatory and/or immunoallergic component". The applicant's references and disclosure in the specification have not shown that these diseases and conditions are treatable with the compounds being claimed.

The applicant also asserts that the examiner must provide evidence supporting the assertion that cancer or precancerous states cannot be prevented with pharmaceutical drugs. However, the burden is on the applicant to enable the

application, not the examiner. It is well known in the art that no pharmaceutical drugs have been found to be able to prevent cancer as well as most other diseases. Applicants have not provided any data, which shows that the drugs being claimed can prevent cancer or precancerous states or the other diseases claimed, or can even treat these diseases. While the applicant's provision of references at paper no. 17 showing the prevention of alopecia is convincing on the subject of drugs being able to prevent alopecia, the applicant has not shown that the drugs being claimed can prevent alopecia, as the applicant has not provided any experimental data.

Rejection of Claims 1-13 and 15-20 under 112, first paragraph

The applicant traverses the enablement rejection alleging that the examiner has not provided evidence or technical reasoning substantiating the lack of enablement. The applicants claim that examples 2-6, 43, 44, 46, 47, 9, 50-59, 61, 62, 66 and 6 entitled the applicant to the full scope of the claims. However, the examples do not enable the full scope of what is being claimed which is R2 and R3 taken together with the adjacent aromatic ring, to form all 5 or 6 membered saturated rings optionally substituted with methyl groups and/or optionally interrupted with an oxygen or sulfur atom, R' and R" taken together to form, with the nitrogen atom, all heterocycle rings, and does not enable electron withdrawing groups such as nitro existing in the ortho position on the aralkyl rings as claimed in claims 6 and 7. In terms of factor 3 and 5, the state of the art and the level of predictability in the art cannot be predicted with any certainty beyond the 70 working examples synthesized. Since no compounds were tested for their

effects as therapeutic agents, the level of predictability in the art is not ascertainable as to their therapeutic value.

In terms of factors 4 and 6, the inventor provides no guidance beyond the working examples in the specification, and provides no examples of how these compounds function as therapeutic compound/compositions and/or therapeutic agents. As a result, one of ordinary skill in the art could not predict how these compounds function as therapeutic agents since this is not taught in the specification, and one of ordinary skill in the art would not be able to synthesize compounds beyond the working examples provided in the specification. With regards to the 7th and 8th wands factor, while the existence of working examples are limited to the various compounds as taught in the specification, an indeterminate quantity of experimentation would be necessary to determine all potential therapeutic compounds/compositions' effects on the diseases claimed.

In terms of the 8th Wands factors, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of predictability in the art of the invention, and the poor amount of direction provided by the inventor. Taking the above factors into consideration, it is not seen where the instant claim is enabled by the instant application.

Moreover, the applicant has included inoperative embodiments in the broad claims, by claiming compounds where the electron-withdrawing groups can exist in the ortho position on an aralkyl or aryl ring.

The applicant alleges that the examiner has not provided any evidence of why one skilled in the art, given the guidance in the specification and the level of skill in the art would find making the compounds unpredictable. However, there is insufficient exemplification to show that all of the ring systems would be attained synthetically.

The IDS references at paper no. 17 have been considered.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (703) 306-5437. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on (703)308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-7922 for regular communications and (703)308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0193.

Alan L Rotman

ALAN L. ROTMAN
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Binta Robinson

August 15, 2003